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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,947	05/02/2001	Stephen Ainsworth	CSI-2016CPI	6172

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EXAMINER	
LINDSEY, RODNEY M	
ART UNIT	PAPER NUMBER
3765	

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.	Applicant(s)	
	09/847,947	AINSWORTH ET AL.	
	Examiner	Art Unit	
	Rodney M. Lindsey	3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-113 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-113 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 31 December 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the one disk-shaped member as set forth in claims 7, 27, 47, 76 and 99 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The use of the trademark NITINOL has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

3. The attempt to incorporate subject matter into this application by reference to a co-owned application (see page 18, lines 15-19 of the specification) is improper because the application was not completely identified.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 1-113 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-113 of copending Application No. 09/847,716. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

6. Applicant is advised that should claim 78 be found allowable, claim 101 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-21, 33-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 2 and in claim 43, line 1 "member" it appears should be --members--. In claim 1, lines 3 and 5 and in claims 4, 5, 9, 14, 19 and 21 "said clip" has no antecedent basis. Claims 13, 33, 53, 82 and 105 are confusing as to how the distally facing surface can oppose the distally facing surface (see lines 3 and 4). Claim 34 is confusing as to whether the "restraint mechanism"

is the same as or is in addition to the "restraint mechanism" already set forth in claim 22. Claim 41 is confusing as to how the "piercing member" is related to the "restraint mechanism" already set forth in claim 22. The last 2 lines of claims 42, 66 and 90 are awkward and confusing. Claims 54, 55 and 56 are confusing as to whether the mechanisms of suture, restraint clip and cylindrical tube are of the second end of the piercing member as set forth in claim 42. Claims 84, 85 and 86 are confusing as to whether the mechanisms of suture, restraint clip and cylindrical tube are of the second end of the flexible member as set forth in claim 66. Claims 106, 107 and 108 are confusing as to whether the mechanisms of suture, restraint clip and cylindrical tube are attached to the second end as set forth in claim 90. Claim 60 is indefinite as to whether the "piercing member" is the same as or is in addition to the "piercing member" set forth in claim 42. In claim 63 "said posterior end" has no antecedent basis. In claim 90, line 13 "said suture" has no antecedent basis. On the last 2 lines of claim 112 and lines 15, 16 of claim 113 "said disengaged configuration" have no antecedent basis.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 1-6, 8, 9 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Shennib et al.

Note Figures 4A-4C of Shennib et al. and the stopper at 22, the proximal members at 23, the open configuration of Figure 4A and the fastened configuration of Figure 4C.

11. Claims 1-3, 5, 6, 13, 14, 17-20, 22, 23, 25, 26, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Komiya.

Note particularly, the stopper 11a, the proximal members 11d, the open configuration of Figure 6 and the closed configuration of Figure 7. With respect to claim 14 note the restraining mechanism 21. With respect to claims 20 and 40 inherently when the mechanism 21 is squeezed the clip will release.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 4 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya in view of Shennib et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to form the apparatus of Komiya of the nickel titanium alloy of Shennib et al. to achieve the advantage of using a biocompatible material.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note particularly, Figures 9-14 of Knodel et al., the combined needle and fastener of Northrup, III et al., Nguyen et al., Lemole and Pasque, Figures 22A-22E of Makower, Figure 12F of Bolduc et al. and the clips of Cushman et al., Zegdi et al. and Acampora et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney M. Lindsey whose telephone number is (703) 305-7818. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John J. Calvert can be reached on (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9301.

Rodney M. Lindsey
Primary Examiner
Art Unit 3765

rml
September 8, 2002